IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* **SARAH BEHNKE,**	:	**CIVIL ACTION**
Plaintiffs,	:	**No. 14-824**
v.	:	
CVS CAREMARK CORPORATION, *et al.*,	:	
Defendants.	:	

Goldberg, J. **April 23, 2020**

MEMORANDUM OPINION

This is a *qui tam* action brought on behalf of the United States of America under the False Claims Act ("FCA"). Relator Sarah Behnke ("Relator") alleges that Defendants CVS Caremark Corporation, CVS Caremark Rx, LLC, CaremarkPCS Health LLC ("Caremark") (collectively, the "Caremark Defendants"), and SilverScript Insurance Company ("SilverScript"), engaged in a scheme to defraud the government by falsely reporting certain price information for prescription drugs subsidized by the government under Medicare Part D. Defendants have moved to dismiss all claims pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), contending that the Complaint fails to meet threshold pleading requirements.

For the reasons stated below, Defendants' motion to dismiss is granted as to Counts I and II against SilverScript and as to Count III against all Defendants. The motion is denied as to Counts I and II against the Caremark Defendants.

I. FACTUAL AND PROCEDURAL BACKGROUND

At this stage of the litigation, I take the facts directly from the Complaint.[1]

A. Relevant Background Regarding Medicare Part D

To understand Relator's allegations, it is necessary to explain—as the Complaint does—the regulatory structure of the Medicare Part D Program, out of which this dispute arises.

Medicare Part D was established by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, for the purpose of providing prescription drug coverage to individuals qualified for Medicare. Unlike Parts A and B of the Act, Part D is a private-market-based program, in which the costs are shared between the government and private health insurers who offer plans, provided those plans meet the requirements of the Medicare Part D Act and its regulations. Private health insurers that offer such plans are referred to as Part D Plan Sponsors ("Plan Sponsors"), and their Medicare Part D plans are referred to as Part D Plans. The government agency responsible for administration of the Medicare Part D Program is the Centers for Medicare and Medicaid Services ("CMS"), which is under the aegis of the U.S. Department of Health and Human Services. (Compl. ¶¶ 28–32.); see also 42 U.S.C. § 1395w-101, *et seq*.

Critical to understanding this case are the ways in which costs are shared between the government and Plan Sponsors. Another judge in this district has summarized this process—consistent with the allegations in the Complaint before me—as follows:

> A Part D sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month ("PMPM") cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. From the bids, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. If the Part D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary must

[1] When deciding a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court must assume the veracity of all well-pleaded facts found in the complaint. Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). Thus, I will assume that all the facts found in the Complaint are true for purposes of Defendants' Rule 12(b)(6) and 9(b) arguments.

> pay the difference as part of a monthly premium. CMS then provides each Part D plan sponsor with advance monthly payments equal to the Part D plan sponsor's standardized bid, risk adjusted for health status, minus the monthly beneficiary premium, estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies.
>
> When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the amount paid to the pharmacy. The PDE is an electronically created document that includes at least thirty-seven fields of information about a specific drug transaction. CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred. If a Part D Plan sponsor's actual costs exceed the estimated costs, the plan sponsor may be able to recoup some of its losses through a risk sharing agreement with CMS. If a Part D Plan sponsor's estimated costs exceed its actual costs by a specified amount, payments to the Part D Plan sponsor for the year are reduced and the Plan sponsor will have to pay back some its estimated payments.
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> Part D Plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with pharmacy benefit managers ("PBM") who provide drugs through mail order and pharmacies. As a condition for receiving its monthly payment from CMS, a Part D Plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must "similarly certify" that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions.

U.S. ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 132–33 (E.D. Pa. 2012); (see also Compl. ¶¶ 36–43, 45–53, 79–85.)

In addition to the PDE reporting requirements described above, "[f]ees, payments, or payment adjustments made after the point-of-sale that change the cost of Part D covered drugs

for Part D sponsors or PBMs must be reported to CMS as Direct or Indirect Remuneration [("DIR")]."[2] (See Compl. ¶¶ 54, 57, 65–66.) CMS relies on this dual-reporting system in order to make sure its payments to Plan Sponsors are accurate:

> The Part D reconciliation process, in particular, is dependent on transaction data summarized on [PDE] records. . . . [but] [o] ften, the Part D sponsor or its pharmacy benefits manager (PBM) receives additional compensation after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug. Examples of such compensation include rebates provided by manufacturers and concessions paid by pharmacies. Under Medicare Part D, this post point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS's calculation of final Medicare payments to Part D plans. . . .
>
> Part D sponsors and PBMs are engaging to a greater extent in arrangements that feature compensation after the point-of-sale, and the value of such compensation is also generally increasing. As a result, CMS has observed a growing disparity between gross Part D drug costs, calculated based on costs of drugs at the point-of-sale, and net Part D drug costs, which account for all DIR.
>
> DIR results from payment arrangements negotiated independent of CMS, between Part D sponsors, PBMs, network pharmacies, drug manufacturers, and other parties involved in the administration of the Part D benefit. . . .
>
> The final plan payments by CMS are, per statute, to be based on the costs actually incurred by Part D sponsors. These actual costs must reflect any applicable DIR. DIR is apportioned only between Medicare and the Part D plan, generally based on the share of the total Part D drug costs that each is responsible for over the course of the payment year.[3]

B. The Alleged Fraud

At the time the Complaint was filed, Relator was employed as Senior Actuary/Head Actuary Medicare Part D for Aetna Life Insurance Company ("Aetna"), a Part D Plan Sponsor. Aetna is not a party to this action. In 2010, Aetna entered into an agreement with the Caremark Defendants, in which Caremark agreed to serve as a PBM for Aetna. (Compl. ¶ 89.) Pursuant to

[2] Fact Sheet, Medicare Part D—Direct and Indirect Remuneration (DIR), CMS.gov (Jan. 19, 2017), https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.

[3] Id.

this agreement, which became effective on January 1, 2011, Caremark agreed to create, contract with, and administer "a network of retail pharmacies . . . to dispense prescriptions to Aetna Part D beneficiaries." (Id.) As permitted by the contract, Caremark set Maximum Allowable Costs ("MAC") prices to be paid by Aetna for multi-source generic drugs dispensed by these pharmacies. (Id. ¶ 94.) The MAC price is the "price Aetna agrees to pay for a prescription for a particular drug," as well as "the price a beneficiary is told is the charge for each specific drug and is the price charged by the pharmacy for the drug when a beneficiary goes to the pharmacy to fill the prescription." (Id. ¶ 94.) Caremark had the ability under the contract to change the MAC prices. (Id. ¶ 95.)

The Agreement also included a list of "retail discount guarantees" for the years 2011 through 2022. (Id. ¶ 96.) These guarantees are "discounts off of reported Average Wholesale Prices ('AWP' or 'AWPs'), an industry benchmark price." (Id.) "[F]or example, in 2011 Caremark guaranteed Aetna would pay no more in the aggregate than 25% of AWP (the flip side of 75% off AWP) for qualifying generic prescriptions." (Id.)

Relator alleges that, over the course of the contract between Aetna and Caremark, Caremark "adjusted the MAC Prices they set for Aetna's Part D business so that the drug prices for Aetna Part D beneficiaries precisely met, but did not exceed, the retail discount guarantees in the contract between Aetna and Caremark." (Id. ¶ 99.) In other words, Caremark set its MAC prices at the maximum allowable under the contract.

Relator claims that she did an investigation of Aetna's arrangement with Caremark and discovered that the MAC prices being charged to Aetna "were significantly higher than prices being charged by other Part D Sponsors to their beneficiaries for the same drugs." (Id. ¶ 101.) Relator allegedly brought this concern to the attention of other employees of Aetna, and Aetna, in

turn, brought this to the attention of the Caremark Defendants during telephone conferences on February 11, 2013 and February 14, 2013. (See id. ¶¶ 102–105.)

During those conferences, Relator allegedly asked representatives of the Caremark Defendants whether they could "negotiate lower pricing with pharmacies or if Caremark had already negotiated discounts similar to what Aetna's competitors had negotiated but were not passing through to Aetna." (Id. ¶ 106.) According to the Complaint, CVS Caremark Corporation's Senior Vice President, Allison Brown, "responded that [Caremark] had negotiated lower prices on Aetna's behalf but it was not required under the contract to provide those prices to Aetna." (Id.) Relator characterizes this as a "virtual admission" that the prices reported by Caremark to CMS were not the prices that Caremark had negotiated with the pharmacies because, "[a]s was clearly understood by the parties, . . . the prices provided to Aetna were also the prices that Aetna reported to CMS as the negotiated prices [with pharmacies]." (Id.) The Caremark Defendants allegedly argued that, "if the Caremark defendants passed better pricing onto Medicare, it would require a concession from Caremark, rather than a concession from the retail pharmacies" and that "improving or increasing the discounts Aetna received would adversely impact the Caremark defendants' earnings due to the Caremark defendants' retail contracting methodology." (Id. ¶ 107.)

Relator further asserts that, after these initial discussions, Aetna informed the Caremark Defendants of its intention to perform a "market check, in order to decide if it would contract with a PBM offering lower drug prices." (Id. at ¶ 112.) In response, the Caremark Defendants allegedly offered to lower Aetna's drug prices by 100 basis points, starting in 2013. (Id.) And, after Aetna initiated the market check anyway, the Caremark Defendants offered to lower Aetna's prices again

by 150 basis points for 2014. (Id.) When the market check was complete, Relator alleges that Aetna and Caremark began negotiating a new contract. (Id. at ¶ 117.)

In these negotiations for a new contract, the Caremark Defendants allegedly offered the addition of a "risk share provision" in which the Caremark Defendants would "reset" the Medicare Part D discount guarantees in the agreement, so that "Aetna would receive 75% of the improvement." (Id. ¶ 117.) When Relator allegedly advised the Caremark Defendants that the 25% that they would retain under this provision "would create an administrative cost that would have to be reported to CMS," "Caremark then stated that it would no longer offer the split it had proposed." (Id. ¶ 118.)

C. Procedural Background of This Action

Relator initiated this action on February 6, 2014, alleging violations of the following provisions of the FCA: 31 U.S.C. § 3729(a)(1)(A) (Count I), 31 U.S.C. § 3729(a)(1)(B) (Count II), and 31 U.S.C. § 3729(a)(1)(G) (Count III).[4] As permitted by the FCA, Plaintiff did so *ex parte* and under seal, allowing the Government the opportunity to investigate.

In April 2018, the Government filed its Notice of Non-Intervention, reserving its right to intervene at a later date and to be provided with a copy of all pleadings and orders in this case until that time. Thereafter, I unsealed the case and the Complaint and ordered it served on Defendants. I have temporarily placed the Complaint back under seal, pending my decision on Defendants'

[4] Under these provisions, Defendants will be held liable if I find that they (1) "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" (Count I); (2) "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" (Count II); and/or (3) "knowingly ma[de], uses[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the Government" (Count III). See 31 U.S.C. § 3729(a)(1)(A)–(B), (G).

unrelated Motion to Seal the Complaint, which the Relator opposes. I will address this motion in a separate Order.

Defendants have moved to dismiss the Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, I will grant in part and deny in part Defendants' motion.

II. LEGAL STANDARD

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). The plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." Id. To determine the sufficiency of a complaint under Twombly and Iqbal, a court must (1) "tak[e] note of the elements a plaintiff must plead to state a claim"; (2) identify the allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth"; and (3) "where there are well-pleaded factual allegations, . . . assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." Burtch v. Milberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011) (internal quotation marks omitted).

It is well-established, however, that *qui tam* actions brought under the FCA must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b). U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 n.9 (3d Cir. 2004) (citing U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998)); U.S. ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 143 (E.D. Pa. 2012). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or

mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." This heightened pleading standard requires plaintiffs to "plead with particularity precise misconduct with which they are charged [in order] to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). "Thus, Rule 9(b) requires, at a minimum, that plaintiffs support their allegations . . . with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." In re Rockefeller Ctr. Properties, Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (internal quotation marks omitted). However, courts will accept allegations on information and belief when "the facts at issue are peculiarly within the defendant's possession." See Lincoln Benefit Life Co. v. AEI Life, LLC, 800 F.3d 99, 107 n.31 (3d Cir. 2015); Rockefeller, 311 F.3d at 216.

III. DISCUSSION

First, I note that Defendants do not challenge that PBMs, like Caremark, are required to certify the "accuracy, completeness, and truthfulness of [price data reported to CMS] and acknowledge that the data will be used for the purpose of obtaining Federal reimbursement." (See Compl. ¶ 84.) In fact, Caremark does not challenge the allegation that it certified the data submitted on behalf of Aetna as complete. (See Compl. ¶¶ 125–128.) As such, this Opinion focuses solely on the sufficiency of the Complaint as to the alleged falsity of Defendants' submission of claims to CMS and the records material to those claims.

A. Counts I and II Against CaremarkPCS Health LLC

1. Fed. R. Civ. P. 9(b)

Defendants first argue that Relator's allegations lack the specificity required by Fed. R. Civ. P. 9(b). Defendants contend that Relator has failed to allege facts regarding Caremark's specific pharmacy contracts, including the particular pharmacies involved, the specific prices for specific drugs negotiated, and the specific Caremark employees involved in negotiating these prices. Defendants explain that, while the Complaint does allege that the inflated MAC prices charged to Aetna were reported to CMS and not the prices actually negotiated with pharmacies, Relator never identifies a "negotiated price" paid to the pharmacy for a drug that was different from what was reported to CMS.

In order to meet the pleading requirements of Rule 9(b) in the FCA context, the United States Court of Appeals for the Third Circuit requires plaintiffs to provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Foglia v. Renal, Ventures Mgmt., LLC, 754 F.3d 153, 157–58 (3d Cir. 2014) (citing U.S. ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)). An FCA claimant is not required to show "the exact content of the false claims in question" to survive a motion to dismiss, as "requiring this sort of detail at the pleading stage would be 'one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates.'" Foglia, 754 F.3d at 156 (quoting Grubbs, 565 F.3d at 190).

For instance, in Foglia v. Renal Ventures Mgmt., LLC, the plaintiff alleged that a dialysis center was not actually using all of the medicine for which it was getting reimbursed by Medicare.

754 F.3d 153, 158 (3d Cir. 2014). The Third Circuit held that the following theory of fraud, although it could be challenged, was sufficient to meet Rule 9(b)'s heightened pleading standard:

> Accepting the factual assertions made by Foglia as true, we have patient logs that show that less Zemplar was used than would be required if it were used in the single use fashion. We know that Medicare will reimburse for the full vial of Zemplar, regardless of whether all of the Zemplar is used, and that this provides an opportunity for the sort of fraud alleged by Foglia. At this point we must assume that Foglia is correct in alleging that Renal did not follow the procedures that it should have followed if it was to harvest the 'extra' Zemplar from the used vials. Although we recognize that this hypothesis could be challenged, it certainly suffices to give Renal notice of the charges against it, as is required by Rule 9(b). This conclusion is further supported by the fact that Renal, and only Renal, has access to the documents that could easily prove the claim one way or another—the full billing records from the time under consideration.

Id.

In U.S. ex rel. Customs Fraud Investigations, LLC v. Vitaulic Co., the relator, a customs fraud investigator, brought a reverse FCA claim against a manufacturer and distributor of pipe fittings, stemming from its failure to pay a "marking duty" on imported products, pursuant to the Tariff Act. 839 F.3d 242, 246–47 (3d Cir. 2016). The relator had not alleged "which shipments, during which time periods, at which ports, were supposedly unlawful" in the complaint. Id. at 258 (internal quotation marks omitted). But, as the Third Circuit recognized, the relator's allegations did explain that "far more Vitaulic pipe fittings on the secondary market should have country-of-origin markings, that the way marking duties are assessed provides an opportunity for fraud, and that only Vitaulic has access to the documents that could prove or disprove the CFI's well-pled allegations." Id. Relying on Foglia, the Third Circuit concluded that these allegations were sufficient to satisfy Rule 9(b). Id.

Here, like the plaintiffs in Foglia and Vitaulic, Relator has pled the alleged theory of fraud with sufficient particularity. Relator claims that MAC prices set by Caremark, charged to Aetna and reported to CMS, were higher than the prices actually paid to pharmacies by Caremark. (See

Compl. ¶¶ 101–116.) As the Complaint alleges, the lower prices that Caremark negotiated with pharmacies were not disclosed to CMS as required, which then resulted in the submission of false claims to CMS and overpayment to Aetna. (See id. ¶¶ 88–128.) For example, Relator specifically alleges that Caremark admitted to negotiating lower prices with pharmacies on Aetna's behalf that were, in turn, not "passed through" to Aetna. (Id. ¶ 106.) Relator also asserts that Caremark knew that Aetna was reporting to CMS the MAC prices charged to Aetna by Caremark, and not the prices Caremark had agreed to with pharmacies. (See id.) According to the Complaint, Caremark stated that it was not required to provide these "pass through" discounts to Aetna and that to do so would adversely impact Caremark's earnings. (Id. ¶ 107.)

Relator also alleges that, in Aetna's negotiations for a new contract, Caremark offered the addition of a "risk share provision" in which Caremark would "reset" the Medicare Part D discount guarantees in the agreement, so that "Aetna would receive 75% of the improvement." (Id. ¶ 117.) When Relator allegedly advised Caremark that the 25% that it would retain under this provision "would create an administrative cost that would have to be reported to CMS," Caremark withdrew the offer. (Id. ¶ 118.)

Relator has pled enough particular details describing the allegedly fraudulent scheme to provide Caremark with adequate notice of the claims against it. See Foglia, 754 F.3d at 158; Vitaulic, 839 F.3d at 258. Relator is not required, at this stage, to plead facts regarding the specific pharmacies that negotiated lower prices with Caremark, the actual negotiated prices, or the specific drugs, especially considering that the pharmacy contracts are exclusively in Caremark's possession. See Vitaulic, 839 F.3d at 258 (not required to plead which shipments, during which time periods, at which ports, were unlawful).

2. Fed. R. Civ. 12(b)(6)

Defendants next argue that, even if the alleged scheme is pled with enough particularity, Relator fails to state a claim for relief under Fed. R. Civ. P. 12(b)(6) on two grounds: (1) Relator's allegations do not support a plausible inference of falsity and (2) Relator's allegations do not support a plausible inference of *knowing* falsity. I address each in turn below.

i. Plausible Inference of Falsity

Defendants contend that Caremark could not have submitted a false claim because Defendants' interpretation of 42 C.F.R. § 423.100 and 42 C.F.R. § 423.308 is correct. (Defs.' Mem., ECF No. 50-1, at 10.) Defendants explain that the "actual cost" required to be reported to CMS by regulation is the "negotiated price," which is the price a pharmacy agrees to receive "for a particular drug." (Id.) Defendants assert that the "mechanism for reporting the 'negotiated price' to CMS is the PDE . . . and CMS guidance expressly states 'the PDE should reflect actual point-of-sale incurred costs.'" (Id. at 10–11.)

Accordingly, Defendants argue that "[a]n aggregate guarantee is simply not the same thing as the actual point-of-sale incurred costs for an individual prescription of a particular drug . . . . Thus, even taking as true [Relator's] non-particularized allegation that Caremark made aggregate guarantees to pharmacies that differed from its aggregate guarantee to Aetna, one cannot reasonably infer that Caremark's PDEs were inaccurate." (Id. at 11.)

I first note that, pursuant to CMS's guidance to Plan D sponsors, "covered drug costs must be incurred and actually paid by the Part D sponsor, net of any direct or indirect remuneration that decreases the costs incurred by the Part D sponsor for the drug." Instructions: Requirements for Submitting Prescription Drug Event Data, CMS, 7 (June 24, 2005).[5] These covered drug costs are

[5] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/DrugCoverageClaimsData/downloads/PDEInstruction_062305.pdf

referred to in the regulations as "gross covered prescription drug cost." 42 C.F.R. § 423.308. "'Gross covered prescription drug costs' mean those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year." Id. These costs are comprised of, in relevant part, "[t]he share of actual costs (as defined by § 423.100)." Id.

The regulations define "actual costs" as the "negotiated price for a covered Part D drug." 42 C.F.R. § 423.100. "Negotiated prices" are prices that meet certain criteria, including prices that "[t]he Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug" and "[a]re inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale." Id.

I also note that "gross covered prescription drug costs" mean those costs that are "actually paid." "Actually paid" is defined as follows:

> Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, . . . or other price concessions or similar benefits offered to some or all purchasers) from any source . . . that would serve to decrease the costs incurred under the Part D plan. Direct and indirect remuneration includes [these discounts and other price concessions] obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

42 C.F.R. § 308.

CMS has commented on the requirement to report certain price concessions excluded from costs "actually paid." In a letter regarding the imposition of per-claim administrative fees, levied

by Part D sponsors (or their intermediaries) on pharmacies, CMS explained that "post-point-of-sale claim adjustments violate our current guidance on negotiated prices." Announcement of CY 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, CMS, 164 (Apr. 1, 2013).[6] "We have clearly stated that negotiated prices . . . must be the amounts ultimately paid to the pharmacy. . . . We believe that the practical effect, if not the intention, of per-claim fees deducted post point-of-sale is overstatement of negotiated prices at point-of-sale. . . . Therefore, we do not believe that per-claim administrative fees that alter the price ultimately paid to the pharmacy are consistent with Part D rules." Id.

In summarizing the comments on this conclusion, CMS notes that Part D sponsors and several PBMs offered "various arguments and regulatory interpretations permitting the reporting of these price concessions as DIR." Id. at 165. CMS acknowledges, based on these arguments, that the "definition of negotiated prices . . . could be interpreted as permitting these kind of arrangements [with pharmacies], despite our intent that negotiated prices transparently reflect all price concessions that a pharmacy has agreed to up-front on a per-drug-claim basis." Id. CMS points out that notice and comment rulemaking would be necessary to require sponsors to consider these fees as part of the negotiated price. Id. However, CMS provides that, in the meantime, while it considers the comments received on this issue and weighs the policy basis for revising the definition of negotiated price, "[CMS] will not consider sponsors non-compliant with our negotiated prices rules as long as all such fees are fully reported as price concessions through DIR reporting . . . ." Id.

[6] https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2014.pdf

Setting aside these observations about the regulatory scheme, even if I were to assume that Defendants' regulatory interpretation is correct, dismissal of Relator's claims at this stage of the case is not appropriate. I make no final determination here as to whether Caremark was required to disclose the prices obtained from pharmacies that were allegedly lower than the MAC prices charged to Aetna. Further factual development is necessary to conclude whether the type of price concessions at issue must be reported to CMS.

What is clear at this stage is that Relator has alleged that Caremark failed to report the lower prices it received from pharmacies on a transactional basis, through PDEs, and also in the aggregate, through DIR. (See Compl. ¶¶ 65–66, 71–78, 122, 125–128.) For example, Relator claims that, as a result of Caremark's alleged scheme, "price concessions or network management fees were not factored into the DIR reconciliation reports" used by CMS to reconcile payments made or due to Aetna. (Id. ¶¶ 125–127.) Relator further alleges "[h]ad [Caremark] provided accurate, non-fraudulent negotiated prices to be reported to CMS, the amount of these payments from CMS would have been lower by an amount estimated to be $25 million in 2012 and $50 million in 2013." (Id. ¶ 128.)

Therefore, for the same reasons discussed above regarding Rule 9(b)'s particularity requirement, I conclude that Relator's allegation of Caremark's failure to report alleged price concessions received from pharmacies in PDE or DIR reports creates a plausible inference of falsity enough to survive dismissal.

ii. Plausible Inference of Knowing Falsity

Defendants argue, in the alternative, that, even if their interpretation of the regulations are wrong, the price reporting rules are unclear, and their meaning is fairly debatable. Accordingly, Defendants contend that Caremark lacks the scienter to knowingly submit a false claim.

I disagree with Defendants and find that Relator has sufficiently alleged scienter. The FCA defines "knowing" or "knowingly" as "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). "Knowing" action under the FCA does not require "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). "Knowledge" may also be pled generally under Fed. R. Civ. P. 9(b). However, allegations of knowledge are still subject to the plausibility standard set forth in Twombly and Iqbal. See U.S. ex rel. Pilecki-Simko v. Chubb Instit., 443 F. App'x 754, 760 n.17 (3d Cir. 2011). The Third Circuit requires "plaintiffs to allege facts that show the court their basis for inferring that the defendants acted with scienter." U.S. ex rel. Pilecki-Simko v. Chubb Instit., No. 06-3562, 2010 WL 1076228, at *7 (D.N.J. Mar. 22, 2010) (internal quotation marks omitted) (citing Burlington, 114 F.3d at 1418).

Here, Relator has pled sufficient facts to demonstrate her basis for inferring that Caremark acted with actual knowledge or reckless disregard for the truth or falsity of its reporting to CMS. (See, e.g., Compl. ¶¶ 112, 117–118.) As discussed above, Caremark allegedly admitted in meetings with Aetna that it had obtained prices from pharmacies lower than the MAC prices charged to Aetna and subsequently reported to CMS. (Id. at ¶¶ 106–107.) Relator also claims that, in response to Aetna's intended "market check" for PBMs offering lower drug prices, Caremark offered to lower Aetna's drug prices by 100 basis points, starting in 2013. (Id. at ¶ 112.) And, after Aetna initiated the market check anyway, Caremark offered to lower prices again by 150 basis points for 2014. (Id.) When the market check was complete, Relator alleges that Aetna and Caremark began negotiating a new contract. (Id. at ¶ 117.) During those negotiations, Caremark allegedly agreed to "reset the guarantee so that Aetna would receive 75% of the improvement." (Id.) Relator claims that, when she advised Caremark that the "25% Caremark

retained in this type of split would create an administrative cost that would have to be reported to CMS," Caremark withdrew its offer. (Id. at ¶ 118.)

Viewing these allegations together in the light most favorable to Relator, I conclude that Relator has sufficiently pled scienter.[7]

B. Counts I and II Against SilverScript Insurance Company

Defendants also seek dismissal of Counts I and II against SilverScript for failure to plead with particularity. SilverScript, a subsidiary of CVS Caremark Corporation, is a Medicare Part D Plan Sponsor. Relator alleges that "[a] Caremark subsidiary" serves as the PBM for SilverScript and that "[t]his PBM or the Caremark defendants" negotiated drug prices with pharmacies on behalf of SilverScript. (Id. ¶ 129.) Relator claims that the negotiated prices with pharmacies on behalf of SilverScript were "essentially the same or slightly higher" than the prices reported for Aetna. (Id.) Relator also asserts that the discounts negotiated with pharmacy chains for

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[7] Defendants also argue that Counts I and II should be dismissed as to Defendant parent corporations, CVS Caremark Corporation ("CVS") and CVS Caremark Rx, LLC ("Caremark Rx"), for Relator's failure to plead with particularity their direct involvement in violating the FCA or to plead facts sufficient to pierce the corporate veil.

Relator alleges that Aetna entered into a PBM contract "whereby [Caremark], [Caremark Rx], and [CVS], agreed to perform certain services to Aetna in connection with Aetna's Part D plan offerings . . . ." (Compl. ¶ 89.) Among the services alleged by Relator are the negotiation of prices with pharmacies and the "accurate[] adjudicate[ion] and process[ing] for payment claims received on behalf of Aetna Part D plan beneficiaries." (Id.) Relator also alleges that Caremark and Caremark Rx created, contracted with, maintained, and administered "a network of pharmacies who agree[d] to dispense prescriptions to Aetna Part D beneficiaries, and the negotiation, on behalf of Aetna, of the prices to be paid to the pharmacies for each drug dispensed to an Aetna beneficiary." (Id.) Relator further claims that CVS, Caremark, and Caremark Rx agreed "to provide drug cost data, including the price paid to the pharmacy for each claim of Aetna Part D beneficiaries (the negotiated price), as required to be submitted to CMS in accordance with [the regulations]" and oversaw "the creation of PDE files and review[ed] and approve[d] the submission of the PDE files to CMS." (Id. ¶¶ 90, 92.) Finally, Relator alleges that the Caremark Defendants, which she identifies in the Complaint as including CVS and Caremark Rx (Id. ¶ 1), knew of the fraud and participated in the meetings with Aetna to discuss it as well as the negotiation of a new PBM contract with Aetna. (See id. ¶¶ 102, 104–107, 112, 117–118.)

Based on these allegations and for the same reasons discussed above as to Counts I and II against Caremark, I conclude that Relator has plausibly pled, with sufficient particularity, CVS and Caremark Rx's involvement in the submission of false claims.

SilverScript Part D beneficiaries "do not vary at all by geographic region or pharmacy chain, suggesting that those prices are not the actual prices that Caremark defendants have negotiated with the pharmacies." (Id.)

Unlike Relator's allegations of the Caremark Defendants' fraudulent reporting as to Aetna, Relator pleads no facts in support of SilverScript's actual knowledge, deliberate ignorance, or reckless disregard for the truth or falsity of its price reporting. Instead, I am asked to assume that, because SilverScript is part of the CVS "conglomerate," it "would have had at least the same visibility into the competitively unreasonable (and thus suspicious) level of its prices as Aetna discovered." (Pl.'s Opp., ECF No. 54, at 25.) Rule 9(b) does not permit this assumption. As such, Counts I and II are dismissed without prejudice against SilverScript. Relator will have an opportunity to amend the Complaint as to these claims, but only if a plausible, good faith amendment is possible.

C. Count III Against All Defendants

Defendants also argue that I should dismiss Count III against all Defendants because Relator has failed to allege any obligation to pay or transmit money to the Government.

On this point, I agree with Defendants. A violation of 31 U.S.C. § 3729(a)(1)(G) makes liable any person who "knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government." A claim brought under this provision is often referred to as a "reverse false claim." "Claims raised under the FCA's reverse false claims provision 'may not be redundant of FCA claims asserted under other provisions of [the FCA].'" U.S. ex rel. Petratos v. Genentech, Inc., 141 F. Supp. 3d 311, 322 (D.N.J. 2015) (quoting U.S. ex

rel. Sobek v. Educ. Mgmt., LLC, No. 10-131, 2013 WL 2404082, at *29 (W.D. Pa. May 31, 2013)). In other words, in order to plausibly allege a violation of § 3729(a)(1)(G), a plaintiff cannot merely recast "his false statement claim" by "essentially alleging that [the defendant] failed to refund the false claims that the government paid." U.S. ex rel. Thomas v. Siemens AG, 708 F. Supp. 2d 505, 514 (E.D. Pa. Apr. 23, 2010). "[T]here must be a clear obligation or liability to the government." Id.

Here, Relator asserts that CMS used data submitted by Caremark on behalf of Aetna to reconcile payments made or due to Aetna for drugs dispensed to Medicare Part D beneficiaries that did not include, as required, the price concessions that Caremark received from pharmacies. (See Compl. ¶¶ 37–39, 57, 64, 69, 126.) Like the plaintiff in U.S. ex rel. Thomas v. Siemens AG,[8] Relator is alleging that Caremark failed to refund the false claims that the government paid, but a failure to refund is not the same as an affirmative obligation to pay the Government.[9] Moreover, the regulation that Relator relies on in the Complaint states only that CMS "may" recover payments made to Plan D sponsors for failure to provide the required drug cost data. (See Compl. ¶ 69

[8] See 708 F. Supp. 2d at 514 ("Thomas appears to be making two arguments in support of liability under the reverse false claim provision. First, he argues that SMS demanded payment based on a fraudulently induced contract each time it requested payment. Consequently, each invoice was inflated, imposing an affirmative obligation on SMS to refund payments it improperly received from the government. Because SMS did not refund the payments, it avoided or decreased its obligation to the government. Second, Thomas maintains that SMS failed to comply with its affirmative obligation under 48 C.F.R. § 552.238–70 to disclose to the government subsequent price reductions it offered to other customers after the government had awarded it contracts and to offer the government a price adjustment.").

[9] Relator cites to my opinion in U.S. ex rel. Class v. Bayada Home Health Care, Inc. to support the sufficiency of her pleading as to Count III. However, in Bayada, unlike here, the relator specifically alleged that the defendant had an obligation to repay or refund the United States and failed to satisfy that obligation. No. 16-680, 2018 WL 4566157, at *16 n.7 (E.D. Pa. Sept. 24, 2018) ("Relators submit that '[Bayada] knew that it had received much needed Medicare dollars in home health PPS payments for patients who did not qualify for the Medicare home health benefit, yet . . . took no action to satisfy its obligations to the United States to repay or refund those payments and instead retained the funds and continued to bill the United States.'")

(citing 42 C.F.R. § 423.343).) Relator has failed to plausibly plead a clear obligation to pay the Government. As such, Count III against all Defendants is dismissed without prejudice. Relator will have an opportunity to amend the Complaint as to this Count, but only if a plausible, good faith amendment is possible.[10]

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is denied as to Counts I and II against the Caremark Defendants. Defendants' motion is granted as to Counts I and II against SilverScript and as to Count III against all Defendants. Relator may amend the Complaint to address the deficiencies identified in this Opinion.

An appropriate Order follows.

[10] Defendants seek dismissal of all claims prior to, at least, 2010. Defendants argue that the alleged obligation to report "pass through" prices did not become effective until January 1, 2010 and Caremark's agreement with Aetna to provide PBM services did not become effective until January 1, 2011. Relator does not oppose the dismissal of all allegations prior to 2010 and concedes that all allegations relating to reimbursement claims submitted through Aetna do not pre-date 2011. (Pl.'s Opp., ECF No. 54, at 30 n.11; Pl.'s Sur-Reply, ECF No. 60, 10.) However, Relator points out that reimbursement claims submitted through other Part D plans, such as SilverScript, date back to 2010. Based on Relator's concessions, I dismiss all claims prior to January 1, 2011 as to the Caremark Defendants and dismiss all claims prior to January 1, 2010 as to SilverScript.